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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,410	04/12/2001	Toyohiro Sawada	019941-000510US	3651

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/834,410

Applicant(s)

SAWADA ET AL.

Examiner

Micah-Paul Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8 and 10-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-8 and 10-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Acknowledgment of Papers Received: Response dated 7/13/05.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1,3-8, 10-19, 21-25 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakashima et al (EP 0 661 045 hereafter 045). The claims are drawn to a time-ed release compression coated oral formulation comprising a core that comprises a drug and an erodible filler, and a coating that comprises a hydrophilic base and a hydrogel-forming polymer.

3. The '045 reference teaches a compression molded oral formulation comprising a core comprising a drug (pg. 3, lin. 1-29), along with solubilizers that help improve the solubility of the drug in water such as citric acid, tartaric acid, and polyethylene glycol (pg 3, lin. 30-43). The core is coated with a hydrogel formulation comprising a hydrophilic base such as polyethylene glycols (pg. 3, lin. 49-pg. 4, lin. 7) and hydrogel-forming polymers with viscosities not less than 1000 cps in 1% aqueous solution such as polyethylene oxides (pg. 4, lin. 8-51). The formulation can include hydrogel-forming polymers in the core such as hydroxypropylmethylcellulose (pg. 3, lin. 37). The formulation further includes yellow iron sesquioxide (pg. 13, lin. 10-15). The drugs include lidocaine, nifedipine, and quinine, agents that are all metabolized by CYP3A4 (pg. 3, lin. 5-25). Upon administration, water is absorbed into the core of the formulation during its stay in the upper intestine, essentially dissolving the core and releasing the drug slowly as it

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travels to the colon (pg 2, lin. 35-40). The drug is present in the formulation in concentrations from 80-85%, the hydrophilic base is present in concentration from 5-80%, the hydrogel-forming polymer is present in concentration greater than 16% and solubilizing agent that aids in water absorption into the core is present in concentrations from 15-90% (pg. 3 lin. 25-pg. 5, lin. 13). The formulation remains within the digestive tract for up to 12 hours and within that time the formulation dissolves 70-100% (figures).

4. Regarding claim 27, it is the position of the examiner that the limitations of the claim, which recites method steps, do not impart patentability onto the claim since the claims is drawn to a time-release product. The method limitations render the claims a product-by-process claim, and as such the process limitations bare little to know patentable weight when taken in light of the prior art disclosures. The prior art teaches a timed-release product comprising an erodible core and a hydrogel coating. Burden is shifted to applicant to provide evidence that the product, regardless of the processing limitations differentiate the instant claims from the product of the reference. For these reason the claims are anticipated.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 20, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Nakashima et al (EP 0 661 045 hereafter '045) and Taniguchi et al (EP 0 709 386 hereafter '386). The claims are drawn to a timed-release composition comprising a core and a coating where the core comprises fused benzazepine derivative.

8. As discussed above the '045 reference discloses a timed-release composition with a core and coating. The drugs listed by the '045 can be metabolized by CYP3A4 and cytochrome P-450. However the reference does not disclose the specific benzazepine derivative of the instant claims.

9. The '366 patent discloses a fused benzazepine derivative, which can be useful as a vasopressin antagonist. The drug can be formulated into tablets using conventional excipients such as sucrose, gelatin and hydroxypropylcellulose (pg. 27, lin. 23 – 37). The drug of the invention can be used in the treatment of various disorders ranging from cerebrovascular disease to renal disorders (pg. 23, lin. 24 – 44). A skilled artisan would be able to include the compound of '386 into the formulation of '045 since the '045 reference uses similar drugs to treat similar disorders.

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10. With these things in mind one of ordinary skill in the art would have been motivated to combine the '386 with the formulation of '045 in order to impart improved treatment of vascular and renal disorders. It would have been obvious to a skilled artisan to combine the suggestions and teachings of the prior art with an expected result of a timed-release formulation with limited drug interaction and improved vascular and renal disorder treatment properties.

Response to Arguments

11. Applicant's arguments filed 7/13/05 have been fully considered but they are not persuasive. Applicant argues that:

- a. The '045 reference does not anticipate the claims.
- b. Since the '045 reference does not anticipate there would be no motivation to combine with the '386 reference.

12. Regarding argument a., it remains the position of the Examiner that the '045 reference does in fact anticipate the claims of the instant invention. Applicant site that 80% of tablet of '045 is gelled during administration, arguing that this *substantially complete* gelation teaches away from the invention. However, since 80% is gelled, logic dictates that 20% of the tablet is un-gelled much like that of the instant claims. Further applicant argues that the '045 reference does not teach a multi-layered tablet. However, a multi-layered tablet is not claims. The claims are drawn to a core tablet, and an outer layer. The further outer layers are purely optional, and bare less effect on the workings of the gelling core of the tablet. The tablet of the '045 comprises a core with fillers such as those recited in the claims that aid in the solubility of the drugs. The core of the '045 is coated with the same polymers with similar viscosities as those of the applicant. The tablet swells and erodes in a manner similar to that of applicant and even

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comprises significantly similar active agents. Within the 12 hours the tablet remains in the GI tract 70% to 100% of the tablet erodes. These disclosures are identical to those of applicant and barring evidence to the contrary will remain anticipatory. The prior art provides a nearly identical formulation within the same field of endeavor in the same structure. Applicant is invited to provide evidence of patentable distinction between the invention of the '045 and those of the instant invention.

13. Regarding argument b., again it is the position of the Examiner that the claims of the invention are obviated by the combination of the prior art. As discussed above the '045 reference provides an identical structure and formulation as that of applicant however, the reference does not disclose the specific fused benzazepine derivatives of claims 20 and 26. However, the '045 reference provides the suggestion of including compounds that are metabolized by CYP3A4 and cytochrome P-450. It would be well within the level of skill in the art to simply substitute the specific compounds of '386 into the formulation since both references teach tablets and comprise similar components. Burden is shifted to applicant to provide evidence of a patentable distinction and any evidence of unexpected results coming from this particular combination. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re*

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Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977). With these things in mind, it remains the position of the Examiner that the claims are obviated by the prior art.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young
Examiner
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